

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

ABBOTT GMBH & CO., KG, ABBOTT)	
BIORESEARCH CENTER, INC., ABBOTT)	C.A. No. 4:09-CV-11340 (FDS)
BIOTECHNOLOGY, LTD.)	
)	
Plaintiffs,)	JURY TRIAL DEMANDED
)	
v.)	
)	
CENTOCOR ORTHO BIOTECH, INC.,)	
CENTOCOR BIOLOGICS, LLC.)	
)	
Defendant.)	
)	

ABBOTT’S TRIAL BRIEF

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In advance of the Final Pre-Trial Conference scheduled for September 7, 2012, and pursuant to the Court's Electronic Order of April 18, 2012 and Local Rule 16.5(f), Plaintiffs Abbott GmbH & Co., KG; Abbott BioResearch Centocor, Inc.; and Abbott Biotechnology, Ltd.¹ (collectively, "Abbott") submit this Trial Brief, enclosing: (I) proposed questions for the voir dire examination of the jury; (II) proposed jury instructions with citations to supporting authority; and (III) proposed special verdict forms for the liability and willful infringement/ damages phases of the trial.

I. PROPOSED VOIR DIRE QUESTIONS

Attached as Exhibit A are Abbott's proposed voir dire questions. Additionally, on August 9, 2012, the parties jointly submitted a short jury questionnaire for the Court's consideration; for the Court's convenience, attached as Exhibit B is a copy of that submission.

II. JURY INSTRUCTIONS

Attached as Exhibit C are Abbott's proposed Preliminary Instructions in the Liability Phase.

The parties have reached agreement on certain of their proposed final jury instructions. Attached as Exhibit D are the parties' Joint Proposed Jury Instructions at the Close of Evidence in the Liability Phase. Attached as Exhibit E are the parties Joint Proposed Preliminary Jury Instructions and Instructions at the Close of Evidence in the Willful Infringement and Damages Phase. To the extent the parties disagree on portions of these instructions, alternative proposals from each party have been incorporated, and the differences between each proposal are highlighted.

¹ Effective June 25, 2012, Abbott Biotechnology, Ltd. changed its name to AbbVie Biotechnology Ltd. (D.I. 368.)

Abbott reserves its right to object to a jury instruction as irrelevant if it turns out there is no evidence on an issue that has a proposed instruction.

III. ABBOTT'S POSITION ON DISPUTED JURY INSTRUCTIONS

For the portions of the proposed instructions on which the parties disagree, Abbott objects to Centocor's proposed jury instructions and requests that Abbott's proposed instructions be adopted based on the case citations and for the following reasons:

A. Abbott's Proposed Preliminary Instructions in the Liability Phase

Abbott proposes a streamlined approach to the preliminary instructions in the liability phase (Ex. C), based largely on a combination of the Federal Circuit Bar Association Model Patent Jury Instructions ("FCBA Model Patent Jury Instructions") and the Joint Proposed Preliminary Instructions the parties agreed to in *Centocor Ortho Biotech, Inc. v. Abbott Laboratories*, CA No. 2:07-cv-139 (E.D. Tex.). Abbott's proposed instructions provide an introduction to what a patent is and how one is obtained (Ex. C, ¶¶ 2-7), without dwelling on issues of infringement that are irrelevant in this case, as the patent video proposed by Centocor would do. Abbott's proposed instructions also provide a clearer and more complete explanation of the evidentiary burden at issue in the liability phase of the trial (Ex. C, ¶¶ 24-25) than do Centocor's. Abbott's instructions also provide a standard explanation of what evidence is (Ex. C, ¶¶ 10-22), which Centocor's instructions do not.

Abbott objects to Centocor's preliminary instructions to the extent that they refer to Abbott seeking money damages and to the second phase of trial being contingent on the jury's verdict in the first phase of trial (*see* Centocor's Summary of Contentions section and Overview of Applicable Law section), for the reasons set forth in Abbott's briefing on its Motion *in Limine* Number 3. Abbott's instructions, on the other hand,

avoid any potential prejudice which could arise if one or more jurors were to conclude that a verdict for Centocor in the first phase would shorten their jury service, by informing the jury that “[t]here will be a second phase of trial, during which Abbott and Centocor will present evidence on additional issues in this case” (§ 28), without revealing what those issues will be. Abbott further objects to Centocor’s Claim Interpretation section as part of the preliminary instructions because a) it will be confusing for the jury to hear prior to the introduction of any of the evidence, b) it is duplicative of the same instruction that the parties propose to be given at the close of evidence, and c) for words that are not defined, it instructs the jurors to apply their common meaning, as opposed to their common meaning as it would be understood by a person of ordinary skill in the art at the time of the invention. Abbott further objects to Centocor’s Overview of Applicable Law section to the extent that it is inconsistent with the parties joint proposed instructions for the close of evidence, and because such instructions would be confusing for the jury to hear prior to the introduction of any evidence. Finally, Abbott objects to Centocor’s Outline of Trial section to the extent that it refers to Abbott’s case as a “rebuttal.” With respect to Centocor’s suggestion, in its Outline of Trial section, that the parties’ attorneys should be permitted to make interim statements “to explain what they believe the evidence has shown or what they believe upcoming evidence will show,” Abbott proposes that the Court and the parties discuss the appropriateness and nature of such statements at the Pretrial Conference.

B. Abbott’s Proposed Instructions at the Close of Evidence in the Liability Phase

1. Written Description

For the written description requirement (Ex. D, Section B(1)), Abbott has proposed an instruction that is simple for the jury to follow, while addressing the relevant aspects of the written description requirement. Abbott's proposed instruction that the written description requirement is satisfied "even though the description may not use the exact words found in the claim" (Ex. D, ¶ 18) comes directly from *Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000) ("[T]he disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue."). The proposed instruction that "[i]t is not necessary that each and every aspect of the claim be discussed, as long as a person of ordinary skill would understand that the missing aspect is necessarily implied in the patent application as originally filed" (Ex. D, ¶ 20) comes from the language of the FCBA Model Patent Jury Instructions at 37, which states: "The full scope of a claim or any particular requirement in a claim need not be expressly disclosed in the original patent application if a person having ordinary skill in the field of technology of the patent at the time of filing would have understood that the full scope or missing requirement is in the written description in the patent application."

Centocor's proposed written description instruction inserts additional, unnecessary language that would only serve to confuse the jury. For instance, Centocor's addition of the sentence "[a] sufficient written description of a genus requires more than a generic statement of an invention's boundaries" (Ex. D, ¶ 23) is duplicative of the instruction that follows, while creating potential confusion about what is in dispute. In *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, the Federal Circuit explained that it previously held "that an adequate written description of a claimed genus requires more than a generic statement of an invention's boundaries" when a patent "failed to describe the claimed genus because it did not distinguish the genus from other materials in any

way except by function” 598 F.3d 1336, 1349-50 (Fed. Cir. 2010) (citing *Regents of the Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997)). The Court explained that as a result, in *Eli Lilly*, “[w]e held that a sufficient description of a genus instead requires the disclosure of . . . a representative number of species falling within the scope of the genus” *Id.* (citing *Eli Lilly*, 119 F.3d at 1568-69). This is the instruction that follows Centocor’s proposed insertion, making the additional proposed language unnecessary and confusing. What is in dispute is whether the specification discloses a sufficient number of representative species, and this is what the focus of the jury instruction should be.

Furthermore, Centocor’s addition of the language “when there is a substantial variation within the genus, the patent must describe a sufficient variety of species to reflect the variation within the genus” (Ex. D, ¶ 24) provides an incomplete statement of the law, as it omits any discussion of the fact that even in an unpredictable art, every species in a genus need not be described in order that a genus meet the written description requirement. *See Eli Lilly*, 119 F.3d at 1568-69. To the extent that the additional language Centocor proposes is adopted, Abbott reserves the right to propose supplemental language, to address any such statements of law that are incomplete.

2. Enablement

Although the parties are largely in agreement on the proposed enablement instruction (Ex. D, Section C), Centocor has proposed the following additional language:

To meet the enablement requirement, Abbott cannot rely on the knowledge of a person of ordinary skill in the art, or on disclosures in the prior art, to serve as a substitute for information that is not in the patent specification. It is the specification, not the knowledge of one skilled in the art, which must supply the novel aspects of an invention in order to constitute adequate enablement. In addition, the patent must provide or describe how to obtain starting materials for making the invention.

(Ex. D, ¶ 28.) This language is an incomplete statement of law because it sets forth the exception to the rule without providing the rule itself. The law is clear that, as a starting point, “a specification need not disclose what is well known in the art.” *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997). Therefore, “the omission of minor details does not cause a specification to fail to meet the enablement requirement.” *Id.* Regardless, this language is unnecessary and only serves to complicate the instruction. If the Court believes that such an additional instruction is necessary, however, Abbott reserves its right to provide an alternative, more complete statement of the law.

3. Obviousness

The parties disagree on two aspects of the proposed instruction on obviousness (Ex. D, Section E). First, Centocor proposes the inclusion of the following language, which is one-sided and incomplete:

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

(Ex. D, ¶ 42.) This instruction focuses on what might be an indication of obviousness in predictable technologies. However, it fails to explain, as the FCBA Model Patent Jury Instructions and Abbott’s proposed instruction do, that this is insufficient for proving obviousness in unpredictable technologies. Therefore, Abbott’s corresponding proposed instruction, “[o]bvious to try is not sufficient in unpredictable technologies” (Ex. D, ¶ 35), which is taken directly from the FCBA Model Patent Jury Instructions at 46, is entirely appropriate in this case.

Second, the parties disagree regarding the language for the instruction on the evidentiary weight that should be accorded to prior art considered versus not considered

by the USPTO (Ex. D, Section E(2)). Centocor proposes to instruct the jury that any prior art it presents that was not considered by the PTO examiner should carry more weight and make it easier to prove obviousness. (Ex. D, ¶ 48.) Abbott's proposed instruction (Ex. D, ¶ 47) addresses the fact that in order to carry more weight, such prior art must not be cumulative of the art that was considered by the PTO examiner, as the case law directs:

That the clear and convincing standard may more easily be met when such non-considered art is *more* pertinent than the cited art means that determination of whether the patent challenger has met its burden turns on the relationship of the uncited art to the claimed invention. . . . To the extent that the examiner's consideration of uncited art is material, the burden is on the challenger to show that that prior art had *not* been considered. The challenger meets that particular burden by showing that the uncited art is more relevant than that cited, just as the patentee defeats the uncited art by showing that its relevancy is equal to or less than that cited.

Lindemann Maschinenfabrik GMBH v. Am. Hoist & Derrick Co., 730 F.2d 1452, 1459-60 (Fed. Cir. 1984) (internal quotation marks and internal citation omitted).

4. Anticipation/Prior Inventorship

The parties propose competing language for the anticipation/prior inventorship instruction (Ex. D, Section F). The language that Centocor proposes in its instruction is inaccurate and misleading. First, Centocor proposes the following instruction: "When there are multiple inventors, each inventor must have contributed to the conception of the invention. The question of priority of a joint invention must be determined from the beginning of the joint activities of the inventors." (Ex. D, ¶ 57). The Court has already determined that this statement of the law is wrong, and we assume that Centocor has proposed this instruction in order to preserve its appellate position on this issue. (*See* Amended Memorandum and Order on Cross-Motions for Summary Judgment (D.I. 341);

Memorandum and Order on Motion for Reconsideration (D.I. 340). *See also* briefing on Abbott's Motion *in Limine* Number 4.)

Second, Centocor's proposed instruction that "[a]n invention of a claim is 'reduced to practice' when an embodiment meeting all claim limitations is actually made and when it is determined that the invention worked for its intended purpose" (Ex. D, ¶ 58) would not be helpful to the jury because it does not explain what "worked for its intended purpose" means. Abbott's alternative instruction, on the other hand – "[a] compound is 'reduced to practice' when it is actually made and when sufficient testing has been done that the inventor appreciated what it had made" (Ex. D, ¶ 53) – provides a more precise explanation of what reduction to practice in this case, in the context of a compound, entails.

Third, Centocor proposes the following inaccurate instruction:

Corroborating evidence of conception and reduction to practice is required. Corroborating evidence should be shown through independent records, physical evidence, and the testimony of non-inventors.

(Ex. D, ¶ 59.) The issue of corroboration is an issue of sufficiency of the evidence for the Court, not the jury, to consider, as evidenced by the fact that this issue consistently comes up only in the context of motions for JMOL or appeals from a patent interference or summary judgment decision. *See, e.g., Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572 (Fed. Cir. 1996) (issue of corroboration addressed as part of appeal of district court's grant of motion for JMOL); *Thomson, S.A. v. Quixote Corp.*, 166 F.3d 1172, 1174 (Fed. Cir. 1999) (party challenging district court's denial of motion for JMOL based on assertion that "evidence is insufficient as a matter of law to support a holding of invalidity under subsection 102(g), *because such testimonial evidence by inventors of their prior invention requires corroboration.*") (emphasis in original); *Sandt Tech., Ltd. v. Resco Metal & Plastics Corp.*, 264 F.3d 1344, 1348 (Fed. Cir. 2001)

(“Because there was sufficient corroboration . . . we affirm the district court’s judgment that claim 1 is invalid.”). Therefore, it is improper to have a corroboration instruction. Furthermore, Centocor’s proposed instruction is inaccurate because it implies that corroborating evidence must be shown through each of “independent records, physical evidence, *and* the testimony of non-inventors.” (Ex. D, ¶ 59 (emphasis added).) However, the rule is not nearly this strict; to show corroboration, a party can provide documentary *or* testimonial evidence. *Loral Fairchild Corp. v. Matsushita Electrical Industrial Co.*, 266 F.3d 1358, 1364 (Fed. Cir. 2001) (“Under the ‘rule of reason,’ the inventor’s testimony must be sufficiently corroborated by independent evidence, but not necessarily documentary evidence.”); *Hahn v. Wong*, 892 F.2d 1028, 1032 (Fed. Cir. 1989) (Corroborating evidence “may consist of testimony of a witness, other than an inventor, to the actual reduction to practice or it may consist of evidence of surrounding facts and circumstances independent of information received from the inventor.”) (internal quotation marks and citation omitted).

Finally, Centocor’s instruction that “[r]eduction to practice follows conception of an invention or, in some circumstances, occurs simultaneously with conception of the invention” (Ex. D, ¶ 58) is unnecessary and not helpful because it is not pertinent to the issues in dispute in this case.

C. Abbott’s Proposed Instructions at the Close of Evidence in the Willful Infringement and Damages Phase

1. Willful Infringement

While the parties are in agreement as to the general instruction on willful infringement, Centocor proposes an additional instruction that lists six factors the jury should consider in determining whether Centocor actually knew or should have known that its actions constituted an unjustifiably high risk of infringement of a valid and

enforceable patent. (Ex. E, ¶ 8.) However, most of these factors concern matters for which Centocor has not presented any evidence to date (i.e., “[w]hether or not Centocor acted in accordance with the standards of commerce for its industry”). Furthermore, providing a list of nonexhaustive factors may mislead the jury to believe other factors should not be considered and may be better left to attorney argument. Based on this reasoning, some pattern jury instructions, such as the Proposed Pattern Patent Civil Jury Instructions for the Seventh Circuit, have declined to provide such a list. *See* FCBA Model Patent Jury Instructions, Committee Comments at 35.

2. Lost Profits

Abbott and Centocor disagree on the language of the final paragraph of their proposed lost profits instruction. Abbott’s instruction (Ex. E, ¶ 19) is more complete than Centocor’s (Ex. E, ¶ 25) because it incorporates language from *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995) (“The patentee need only show that there was a reasonable probability that the sales would have been made ‘but for’ the infringement. . . . The burden then shifts to the infringer to show that the inference is unreasonable for some or all of the lost sales.”) (internal citation omitted), which Centocor’s instruction touches on much more briefly, and language from *Kaufman Co. v. Lantech, Inc.*, 926 F.2d 1136, 1141-42 (Fed. Cir. 1991)) (“Any doubts regarding the calculatory precision of the damage amount must be resolved against the infringer”), which Centocor’s completely omits.

IV. SPECIAL VERDICT FORMS

Abbott proposes that the verdict form attached as Exhibit F be used at the conclusion of the liability phase, and that the verdict form attached as Exhibit G be used at the conclusion of the willful infringement and damages phase.

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that, on August 29, 2012, this document (filed through the ECF system) will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Robert J. Gunther, Jr.

Robert J. Gunther, Jr.